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Attorneys for Individual and Representative Plaintiff Mircea Muresan

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MIRCEA MURESAN, on behalf of himself and all others similarly situated,

Plaintiff,

v.

MERCK & CO., INC., SCHERING- PLOUGH CORPORATION, and MERCK/SCHERING-PLOUGH PHARMACEUTICALS

Defendant.

Case No. CV 08 0929

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Mircea Muresan brings this class action complaint on behalf of himself and on behalf of the proposed Class and California Subclass defined herein and alleges as follows:

NATURE OF THE ACTION

1. Vytorin is a combination drug consisting of the anti-cholesterol drugs Zocor and Zetia. A clinical trial of Vytorin conducted by Defendants and completed in April 2006 showed Vytorin to be no more effective than Zocor alone at preventing the plaque buildup along arterial walls that causes heart attacks and strokes. Defendants chose, however, not to release the results of the clinical trial and to heavily market Vytorin as more effective at lowering cholesterol than Zocor alone. Defendants did not make public the results of the Vytorin clinical trial until January 2008, a month after the House of Representatives' Committee on Energy and Commerce began an investigation. As a result, Plaintiff and class members collectively spent billions of dollars to purchase Vytorin rather than the less expensive generic version of Zocor (simvastatin).

JURISDICTION

2. This Court has jurisdiction over this action under the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1965(a). The Court also has jurisdiction over this action under the Class Action Fairness Act, 28 U.S.C. § 1332(d). The aggregated claims of the individual class members exceed the sum value of $5,000,000, exclusive of interests and costs, and this is a class action in which more than two-thirds of the proposed plaintiff classes, on the one hand, and Defendants, on the other, are citizens of different states.

VENUE

3. Venue is proper in this District under 18 U.S.C. § 1965(a) because Defendants are found, have agents, or transact their affairs in this District, in that Defendants business contacts with this District have been repeated, substantial, and continuous over a period of years. In the absence of RICO jurisdiction, venue would also be proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District, in that Defendants advertised Vytorin to Plaintiff in this district and Plaintiff purchased and took Vytorin in

this District. In addition, Defendants' contacts with the District are sufficient to subject Defendants to personal jurisdiction in this Court.

INTRADISTRICT ASSIGNMENT

4. Assignment is proper to the San Francisco or Oakland divisions of this District under Local Rule 3-2(c)-(d), as this action arises in Contra Costa County. A substantial part of the events or omissions giving rise to Plaintiff's claims occurred in Contra Costa County, in that Defendants advertised Vytorin to Plaintiff in Contra Costa County and Plaintiff purchased and took Vytorin in Contra Costa County.

PARTIES

5. Plaintiff Mircea Muresan is a citizen of California residing in Pleasant Hill.

6. Defendant Merck & Co., Inc. ("Merck") is a corporation organized under the laws of the State of New Jersey and maintains its headquarters in Whitehouse Station, New Jersey.

7. Defendant Schering-Plough Corporation ("Schering") is a corporation organized under the laws of the State of New Jersey and maintains its headquarters in Kenilworth, New Jersey.

8. Defendant Merck/Schering-Plough Pharmaceuticals is a joint venture partnership between Merck and Schering. Its headquarters are located at 351 N. Sumneytown Pike, Northwales, Pennsylvania.

FACTUAL ALLEGATIONS

Zocor

9. Zocor is an anti-cholesterol drug developed and patented by defendant Merck. By inhibiting the body's natural production of cholesterol, Zocor prevents the buildup of fatty plaque deposits in the arteries, which is the most common cause of heart disease and death in the U.S. and a leading cause of stroke.

10. Merck was wildly successful in marketing the use of Zocor to reduce the risk of heart disease and stroke by lowering cholesterol level. FDA approved in 1991, by 1995, Zocor had been prescribed for 3.1 million patients worldwide. For years, Zocor was Merck's best-selling drug, reaching

annual worldwide revenues of over $5 billion.

11. With the patent for Zocor set to expire on June 23, 2006, Merck stood to lose billions from competing sales of generic Zocor (simvastatin).

Vytorin

12. In May 2000, Merck and Schering entered into agreements to jointly pursue the development and marketing of Zocor as a combination tablet with another drug. Merck and Schering announced that the development and marketing activities under their partnership agreement would be conducted through a partnership, called Merck/Schering-Plough Pharmaceuticals, which would be equally owned and managed by Merck and Schering. They further announced that the partnership would draw upon the research expertise and sales force of each company, pursuing new products to compete in the cholesterol-management market that would not otherwise be developed, and that Merck and Schering would co-promote the new medicines resulting from the partnership.

13. In 2004, Defendants introduced Vytorin, a combination drug comprised of Zocor and another anti-cholesterol drug called Zetia. Unlike Zocor, the patent rights to Zetia, owned by Schering, do not expire until 2013.

14. Vytorin was approved for sale by the FDA on July 23, 2004, and a year later had become the third best-selling anti-cholesterol drug in the U.S., behind only Lipitor and Zocor.

The Enhance Clinical Trial

15. Beginning in 2004, Defendants began a clinical trial on Vytorin's effectiveness at reducing the buildup of plaque deposits along arterial walls when compared to Zocor alone.

16. In this so-called "Enhance" study, ultrasound imaging was used to measure arterial wall thickness at three sites in the carotid arteries of 720 high-cholesterol patients over a two-year period. Roughly half of the patients received Vytorin (ezetimibe / simvastatin) while the rest received Zocor (simvastatin).

17. Completed in April 2006, the Enhance study showed no statistically significant difference between the two treatment groups. That is, Vytorin proved no more effective than Zocor alone at preventing the buildup of the plaque deposits that cause heart disease and stroke.

Defendants' Failure to Publicly Disclose the Enhance Results

18. Defendants knew that if the Enhance results were publicly disclosed, consumers would purchase the less expensive simvastatin (generic Zocor) rather than pay a premium for the brand name drug (Vytorin).

19. Defendants instead concealed and otherwise avoided publicly disclosing the Enhance results. This was possible, in part, because unlike most clinical trials, an oversight board independent of the corporate sponsor was not named to oversee the scientific aspects of the study. Defendant Schering has recently said that independent oversight boards were not named for Enhance because unusual events were not expected.

Defendants' Misleading Vytorin Advertising

20. Although Defendants were aware that the Enhance results showed Vytorin to be no more effective than Zocor alone at preventing the buildup of the plaque deposits that cause heart disease and stroke, Defendants misleadingly marketed Vytorin as superior to Zocor.

21. A seemingly omnipresent series of television commercials, known as the "two sources" advertising campaign, continuously informed consumers: "There are two sources of cholesterol: food and family. Vytorin treats both."

22. Defendants advertised that "Vytorin lowers bad cholesterol more than Zocor alone"; that "Vytorin was clinically proven to reduce LDL (bad) cholesterol more than Zocor alone"; and that "unlike Zocor, only Vytorin helps block the absorption of cholesterol that comes from food AND reduces the cholesterol your body makes naturally based on family history."

23. As the Rep. Bart Stupak, Chair of the House Energy and Commerce Committee Subcommittee on Oversight and Investigations, has put it, "The assumption [from these advertisements] is that lower cholesterol means reduced plaque means reduced risk of heart attack and stroke." Defendants knew, however, that in the Enhance clinical trial, lower cholesterol did not translate into lower buildup of the plaque that causes heart attack and stroke.

Defendants Finally Disclose The Ensure Results

24. It was not until January 14, 2008, that Defendants finally released the results of the Enhance study.

25. The next week, Defendants pulled their Vytorin television advertisements off the air.

26. Defendants did not disclose the Enhance results until just after the U.S. House of Representatives' Committee on Energy and Commerce commenced a formal investigation into why the data had not yet been released.

27. The Chair of the Subcommittee on Oversight and Investigations has stated that informal investigation began in the fall of 2007, after "medical people assigned to the staff who had been hearing rumblings in the medical community. Cardiologists, for example, who might have had a patient or two enrolled in the study had sent the information in a long time ago and never heard back about the results. They were wondering: what happened?"

28. Prior to the fall of 2007, Defendants had not even registered the Enhance study on the U.S. federal government website clinicaltrials.gov, as was customary and now required of all clinical trials.

29. Facing tremendous criticism from Congress, the media, and the medical community for not releasing the Enhance data earlier, Defendants have provided various excuses.

30. According to a press release and "Enhance Chronology" published by Defendants, the Enhance results were not released because Defendants wanted time to re-examine measurements that seemed implausible to them; to improve data quality that was reported as "similar to that in other IMT trials"; to consider amending the study protocol; and to consider changing the data measurements that would be reported.

Plaintiff's Resulting Monetary Damages

31. Plaintiff Mircea Muresan was prescribed and began taking Vytorin in or around July 2007. As a result of Defendants' conduct, Plaintiff purchased and took Vytorin rather than the less expensive generic Zocor (simvastatin), paying more for his anti-cholesterol medication than he otherwise would have.

CLASS ACTION ALLEGATIONS

32. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of himself and all others similarly situated persons as members of a Class initially defined as follows:

All United States residents who purchased Vytorin On Or After July 23, 2006, and Before January 14, 2008.

33. Plaintiff also brings this action on behalf of a California Subclass initially defined as follows:

All California residents who purchased Vytorin On Or After July 23, 2006, and Before January 14, 2008.

34. Excluded from both classes are all claims for personal injury. Also excluded are Defendants; any affiliate, parent, or subsidiary of Defendants; any entity in which Defendants have a controlling interest; any officer, director, or employee of Defendants; any successor or assign of Defendants; and any Judge to whom this case is assigned as well as his or her immediate family.

35. **Numerosity of the Class—Fed. R. Civ. P. 23(a)(1).** Members of the Class and California Subclass are so numerous and widely dispersed that joinder of them in one action is impracticable. Just in the week ending January 11, 2008 (immediately before Defendants publicly released the results of the Enhance study), a reported 397,533 prescriptions were written for Vytorin throughout the United States.

36. **Existence and Predominance of Common Questions of Law and Fact—Fed. R. Civ. P. 23(a)(2), 23(b)(3).** Common questions of law and fact exist as to all members of the Class and California Subclass and predominate over questions affecting only individual class members. These common questions include the following:

a. When Defendants knew that the Enhance clinical trial shows Vytorin to be no more effective than Zocor alone at preventing the buildup of the plaque deposits that cause heart disease and stroke;

b. Whether it would be a material fact to a reasonable person and/or reasonable doctor that the Enhance clinical trial shows Vytorin to be no more effective than Zocor alone at preventing the buildup of the plaque deposits that cause heart disease and stroke;

c. Whether Defendants had a duty to disclose the Enhance results to the public earlier than it did;

d. Whether Defendants' marketing of Vytorin as superior to Zocor is misleading in light of the Enhance results;

e. Whether Defendants' committed wire fraud by using internet, radio, and television advertisements in furtherance of a scheme or artifice to increase sales of Vytorin under false or fraudulent pretenses;

f. Whether Defendants' conducted or conspired to conduct the Merck/Schering-Plough Pharmaceuticals enterprise's affairs through a pattern of racketeering activity in violation of RICO;

g. Whether Defendants' conduct was unfair, unlawful, or fraudulent in violation of California's Unfair Competition Law; and

h. Whether Defendants' conduct violated the Consumers Legal Remedies Act by, among other things, representing that Vytorin had benefits which it does not have or disparaging generic Zocor (simvastatin) with misleading statements of fact.

37. **Typicality—Fed. R. Civ. P. 23(a)(3).** Plaintiff is a member of the Class and California Subclass. Plaintiff's claims are typical of the claims of the other class and subclass members because Plaintiff and all class and subclass members purchased Vytorin, paid more for Vytorin than they would have for generic Zocor (simvastatin), and were injured by the same wrongful acts and practices in which Defendants engaged, as alleged herein.

38. **Adequacy of Representation—Fed. R. Civ. P. 23(a)(4).** Plaintiff will fairly and adequately protect the interests of the Class and California Subclass. Plaintiff's interests are coincident with, and not antagonistic to, those of class and subclass members. In addition, Plaintiff has retained attorneys who are experienced and competent in the prosecution of complex and class litigation. Neither Plaintiff nor his attorney has any conflict in undertaking this representation.

39. **Superiority—Fed. R. Civ. P. 23(b)(3).** A class action is superior to all other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by individual class and subclass members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendants, so it would be impracticable for the members of the Class or California Subclass to individually seek redress for

Defendants' wrongful conduct. Even if the members of the Class or California Subclass could afford individual litigation, the court system could not. Individualized litigation creates a potential for inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

40. In the alternative, the Class and California Subclass may be certified because:

a. The prosecution of separate actions by the individual members of the Class and California Subclass would create a risk of inconsistent or varying adjudication with respect to individual class and subclass members, which would establish incompatible standards of conduct for Defendants;

b. The prosecution of separate actions by individual class and subclass members would create a risk of adjudications that would, as a practical matter, be dispositive of the interests of other class and subclass members not parties to the adjudications, or would substantially impair or impede their ability to protect their interests;

c. Defendants have acted or refused to act on grounds generally applicable to the Class and California Subclass, thereby making appropriate final injunctive relief with respect to the members of the Class and California Subclass as a whole; and

d. The claims of class and subclass members are comprised of common issues that are appropriate for certification under Rule 23(c)(4).

FIRST CAUSE OF ACTION

(Violations of RICO, 18 U.S.C. § 1962(c), Against Defendants Merck and Schering On Behalf of the Class)

41. Plaintiff incorporates by reference and realleges all paragraphs previously alleged herein.

42. Defendants Merck and Schering are "persons" under 18 U.S.C. § 1961(3).

43. Merck/Schering-Plough Pharmaceuticals is an "enterprise" under 18 U.S.C. § 1961(4). The Merck/Schering-Plough Pharmaceuticals enterprise is engaged in, and its activities affect, interstate or foreign commerce.

44. The Merck/Schering-Plough Pharmaceuticals enterprise is equally owned, managed, and controlled by Defendants Merck and Schering. The material decisions guiding the operation of the Merck/Schering-Plough Pharmaceuticals enterprise—including decisions concerning the research, sale, and marketing of Vytorin—are made by Defendants Merck and Schering jointly.

45. The actions of Defendants Merck and Schering described above constitute wire fraud under 18 U.S.C. § 1343, in that they constitute or are in furtherance of a scheme or artifice to defraud or obtain money by means of false or fraudulent pretenses or representations, furthered or executed through Defendants' transmission of writings, signals, or data by means of wire, radio, or television communication.

46. By representing through frequent internet, radio, and television advertisements that Vytorin lowers bad cholesterol more than Zocor alone and that unlike Zocor, only Vytorin treats both sources of cholesterol, while fraudulently concealing that the Enhance clinical trial showed Vytorin to be no more effective than Zocor at preventing the plaque buildup that causes heart disease and stroke, in furtherance of a scheme or artifice to procure revenue through the sale of Vytorin by false or fraudulent pretenses, Defendants have committed wire fraud thousands or even millions of times over the past two years and thus engaged in a "pattern of racketeering activity" as defined in 18 U.S.C. § 1961(5).

47. Therefore, Defendants Merck and Schering have violated 18 U.S.C. § 1962(c) in that they are associated with an enterprise engage in, or the activities of which affect, interstate or foreign commerce, and have conducted or participated, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity.

48. Plaintiff and Class members have been injured in their business or property by reason of Defendants' violations of 18 U.S.C. § 1962(c). Accordingly, Plaintiff, on behalf of himself and all others similarly situated, seeks treble damages and costs of suit, including a reasonable attorneys' fees.

SECOND CAUSE OF ACTION

(Violations of RICO, 18 U.S.C. § 1962(d), Against Defendants Merck and Schering On Behalf of the Class)

49. Plaintiff incorporates by reference and realleges all paragraphs previously alleged herein.

50. Defendants Merck and Schering agreed to participate in the affairs of the Merck/Shering Pharmaceuticals enterprise described above through the commission of two or more predicate offenses

by either of them. In particular, Defendants agreed to commit wire fraud thousands or even millions of times over the past two years, as described above, and in fact did so.

51. Therefore, Defendants Merck and Schering have conspired to violate 18 U.S.C. § 1962(c), in violation of 18 U.S.C. § 1962(d).

52. Plaintiff and Class members have been injured in their business or property by reason of Defendants' violations of 18 U.S.C. § 1962(d). Accordingly, Plaintiff, on behalf of himself and all others similarly situated, seek treble damages and costs of suit, including a reasonable attorneys' fees.

THIRD CAUSE OF ACTION

(Violation of California's Consumers Legal Remedies Act Against All Defendants On Behalf of the California Subclass)

53. Plaintiff incorporates by reference and realleges all paragraphs previously alleged herein.

54. Vytorin is a "good" under Cal. Civ. Code § 1761(a).

55. Plaintiff and other California Subclass members are "consumers" under Cal. Civ. Code § 1761(d).

56. Plaintiff and other California Subclass members' purchases of Vytorin constitute "transactions" under Cal. Civ. Code § 1761(e).

57. Defendants' conduct, as alleged herein, violates the Consumers Legal Remedies Act, Cal. Civ. Code § 1770(a), in that Defendants:

a. Represented that goods have characteristics, uses or benefits they do not have;

b. Represented that goods are of a particular standard, quality, or grade when they are of another;

c. Disparaged the goods of another by false or misleading representations of fact; and

d. Advertised goods with intent not to sell them as advertised.

58. Defendants advertised and represented that Vytorin was superior to generic Zocor (simvastatin), Lipitor, Crestor, and any other anti-cholesterol drug because it was the "only" anti-cholesterol drug that treated both sources of cholesterol.

59. Defendants advertised and represented that Vytorin was superior because it was a combination drug that lowered "bad" cholesterol more than taking generic Zocor (simvastatin), Lipitor, Crestor, or any other anti-cholesterol drug alone.

60. Plaintiffs, other California Subclass members, and their doctors reasonably assumed that a drug that treats two sources of cholesterol rather than just one, and that lowers bad cholesterol more than other medications acting alone, would be superior at preventing the plaque buildup along arterial walls that causes heart attacks and strokes.

61. When making their advertisements and representations, Defendants knew or should have known that the Enhance clinical trial showed Vytorin to be no more effective than Zocor (simvastatin) alone at preventing the plaque buildup along arterial walls that causes heart attacks and strokes.

62. The fact that a clinical trial showed Vytorin to be no more effective than Zocor (simvastatin) alone at preventing the plaque buildup along arterial walls that causes heart attacks and strokes would have been a material fact to Plaintiff, other California Subclass members, and their doctors.

63. Defendants were under a duty to disclose to Plaintiffs and other California Subclass members that the Enhance study showed Vytorin to be no more effective than Zocor (simvastatin) alone at preventing the plaque buildup along arterial walls that causes heart attacks and strokes. Defendants owed this duty because:

a. Defendants made representations about Vytorin's superior ability to lower bad cholesterol when compared to Zocor (simvastatin) alone without disclosing that this did not translate into lower levels of the arterial plaque that causes heart attacks and strokes in the Enhance clinical trial;

b. Defendants were in a superior position to know the results of the Enhance clinical trial; and

c. The health and safety of Plaintiffs and other California Subclass members, who were subject to the potential side effects of both Zocor and Zetia by taking the combination drug Vytorin, was implicated by the Enhance clinical trial results.

64. As a direct and proximate cause of Defendants' misconduct, Plaintiff and the California Subclass have suffered economic harm. Accordingly, Plaintiff, on behalf of himself and the California Subclass, seeks injunctive and declaratory relief, attorneys' fees and costs of suit, and other non-monetary relief as appropriate.

FOURTH CAUSE OF ACTION

(Violation of California's Unfair Competition Law Against All Defendants)

65. Plaintiff incorporates by reference and realleges all paragraphs previously alleged herein.

66. Defendants' acts and practices as alleged in this Complaint constitute unlawful, unfair, and/or fraudulent business practices in violation of the Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, et seq.

67. Defendants engaged in unlawful business practices by, among other things:

a. Engaging in conduct, as alleged herein, that violates the Racketeer Influenced and Corrupt Organizations Act;

b. Engaging in conduct, as alleged herein, that violates the Consumers Legal Remedies Act; and

c. Engaging in conduct that constitutes fraudulent concealment and nondisclosure.

68. Defendants engaged in unfair business practices by, among other things:

a. Engaging in conduct where the utility of that conduct is outweighed by the gravity of the consequences to Plaintiff and other members of the California Subclass;

b. Engaging in conduct that is immoral, unethical, oppressive, unscrupulous, or substantially injurious to Plaintiff and other members of the California Subclass; and

c. Engaging in conduct that undermines or violates the stated policies underlying the CLRA, which seeks to protect consumers against unfair and sharp business practices and to promote a basic level of honesty and reliability in the marketplace, as well as the policies underlying the common law, such as fraudulent concealment and nondisclosure.

69. Defendants engaged in fraudulent business practices by engaging in conduct that was and is likely to deceive consumers and their doctors acting reasonably under the circumstances.

70. As a direct and proximate cause of Defendants' misconduct, Plaintiff and other members of the California Subclass have suffered economic harm. Accordingly, Plaintiff, on behalf of himself and the California Subclass, seeks equitable relief, including restitution of all money wrongfully

acquired by Defendants as a result of its unlawful, unfair, and fraudulent business practices, as well as recovery of attorneys' fees and costs of suit.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, pray for a judgment against Defendants as follows:

a. An order certifying the Class and appointing Plaintiff and his counsel to represent the Class;

b. Actual and treble damages as plead or as the Court may deem proper;

c. Restitution as plead or as the Court may deem proper;

d. Other equitable relief as plead or as the Court may deem proper;

e. Attorneys' fees and costs of suit, including expert witness fees; and

f. Such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all claims so triable.

DATED: February 13, 2008

Respectfully submitted,

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